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Purtzer

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(54) **MEDICAL DEVICE INCLUDING A SOLDERABLE LINEAR ELASTIC NICKEL-TITANIUM DISTAL END SECTION AND METHODS OF PREPARATION THEREFOR**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

2,938,850 A 5/1960 Hans
3,203,884 A 8/1965 Heinz et al.

(Continued)

FOREIGN PATENT DOCUMENTS

CN 101115869 A 1/2008
CN 101554685 A 10/2009

(Continued)

OTHER PUBLICATIONS

Duerig, T. W., Melton, K. N., & Stöckel, D. (2013). *Engineering aspects of shape memory alloys*. Butterworth-Heinemann, 414-419.

(Continued)

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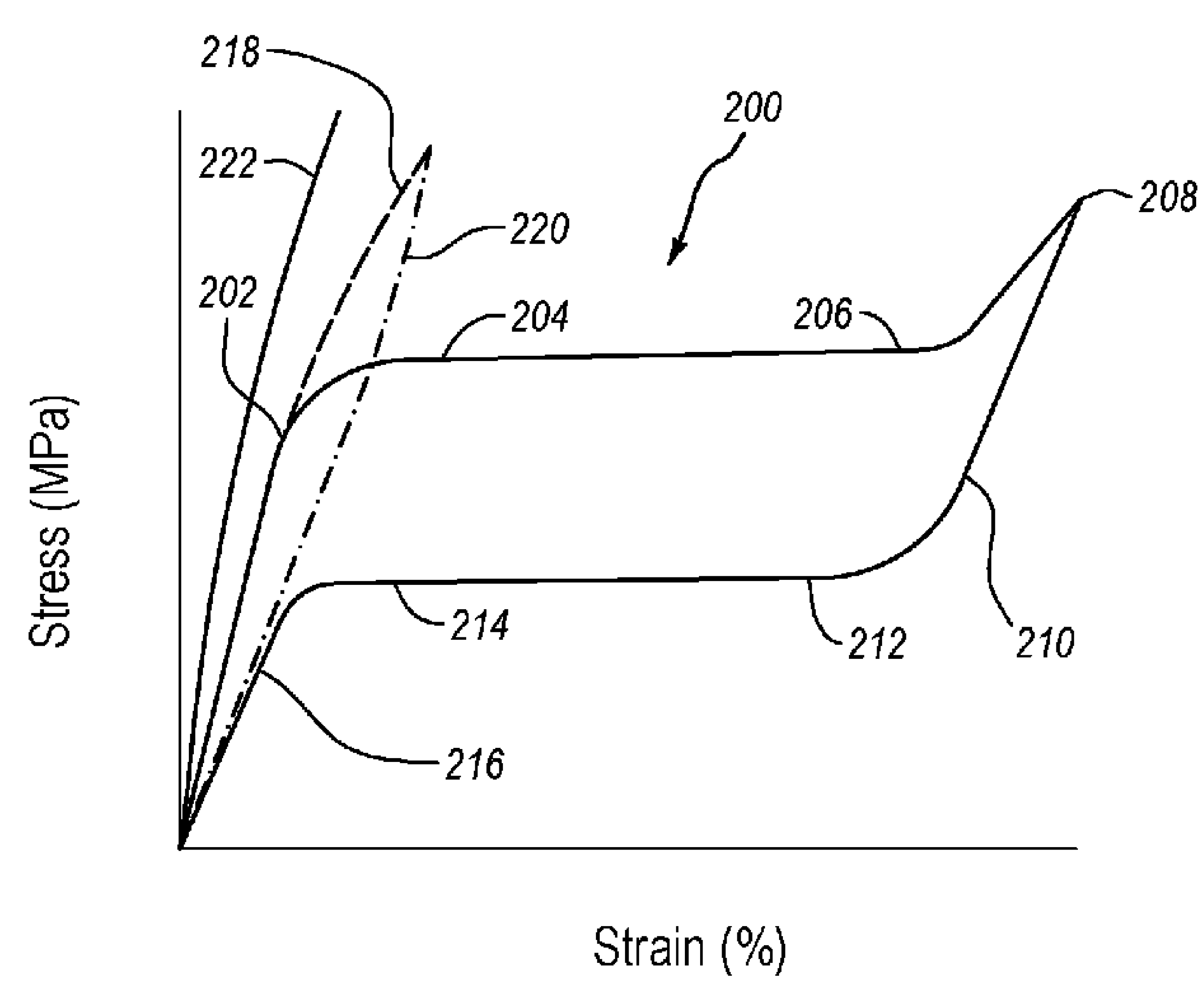
(57) **ABSTRACT**

Shapeable guide wire devices and methods for their manufacture. Guide wire devices include an elongate shaft member having a shapeable distal end section that is formed from a linear pseudoelastic nickel-titanium (Ni—Ti) alloy that has linear pseudoelastic behavior without a phase transformation or onset of stress-induced martensite. Linear pseudoelastic Ni—Ti alloy, which is distinct from non-linear pseudoelastic (i.e., superelastic) Ni—Ti alloy, is highly durable, corrosion resistant, and has high stiffness. The shapeable distal end section is shapeable by a user to facilitate guiding the guide wire through tortuous anatomy. In addition, linear pseudoelastic Ni—Ti alloy is more durable tip material than other shapeable tip materials such as stainless steel.

14 Claims, 6 Drawing Sheets



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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,612,058	A	10/1971	Ackerman
3,635,703	A	1/1972	Pissarevsky
3,937,628	A	2/1976	Watanabe et al.
4,127,459	A	11/1978	Jumer
4,330,381	A	5/1982	Jumer
4,654,092	A	3/1987	Melton
4,685,977	A	8/1987	Chang
4,846,186	A	7/1989	Box et al.
4,854,330	A	8/1989	Evans, III et al.
4,967,753	A	11/1990	Haase et al.
5,061,275	A	10/1991	Wallsten et al.
5,067,489	A	11/1991	Lind
5,069,226	A	12/1991	Yamauchi et al.
5,147,317	A	9/1992	Shank et al.
5,171,383	A	12/1992	Sagaye et al.
5,174,295	A	12/1992	Christian et al.
5,174,302	A	12/1992	Palmer
5,184,621	A	2/1993	Vogel et al.
5,238,004	A	8/1993	Sahatjian et al.
5,287,858	A	2/1994	Hammerslag et al.
5,330,826	A	7/1994	Taylor et al.
5,353,798	A	10/1994	Sieben
5,353,808	A	10/1994	Viera
5,354,623	A	10/1994	Hall
5,404,887	A	4/1995	Prather
5,421,955	A	6/1995	Lau et al.
5,433,200	A	7/1995	Fleischhacker, Jr.
5,449,369	A	9/1995	Imran
5,480,382	A	1/1996	Hammerslag et al.
5,514,154	A	5/1996	Lau et al.
5,569,295	A	10/1996	Lam
5,603,721	A	2/1997	Lau et al.
5,618,299	A	4/1997	Khosravi et al.
5,628,787	A	5/1997	Mayer
5,630,840	A	5/1997	Mayer
5,636,641	A	6/1997	Fariabi
5,649,952	A	7/1997	Lam
5,666,969	A	9/1997	Urick et al.
5,673,707	A	10/1997	Chandrasekaran
5,695,111	A	12/1997	Nanis et al.
5,716,400	A	2/1998	Davidson
5,716,417	A	2/1998	Girard et al.
5,725,572	A	3/1998	Lam et al.
5,728,158	A	3/1998	Lau et al.
5,735,893	A	4/1998	Lau et al.
5,746,701	A	5/1998	Noone
5,759,192	A	6/1998	Saunders
5,766,238	A	6/1998	Lau et al.
5,776,080	A	7/1998	Thome et al.
5,788,654	A	8/1998	Schwager
5,797,857	A	8/1998	Obitsu
5,799,386	A	9/1998	Ingersoll et al.
5,803,344	A	9/1998	Stankavich et al.
5,824,077	A	10/1998	Mayer
5,849,037	A	12/1998	Frid
5,858,556	A	1/1999	Eckert et al.
5,865,767	A	2/1999	Frechette et al.
5,876,432	A	3/1999	Lau et al.
5,891,055	A	4/1999	Sauter
5,891,191	A	4/1999	Stinson
5,916,178	A	6/1999	Noone et al.
5,984,973	A	11/1999	Girard et al.
5,985,126	A	11/1999	Bleck et al.
6,004,279	A	12/1999	Crowley et al.
6,027,528	A	2/2000	Tomonto et al.
6,139,511	A	10/2000	Huter et al.
6,183,353	B1	2/2001	Frantzen
6,214,200	B1	4/2001	Altena et al.
6,221,096	B1	4/2001	Aiba et al.
6,234,981	B1	5/2001	Howland
6,287,331	B1	9/2001	Heath
6,355,058	B1	3/2002	Pacetti et al.
6,375,826	B1	4/2002	Wang et al.
6,390,992	B1	5/2002	Morris et al.
6,419,693	B1	7/2002	Fariabi
6,500,130	B2	12/2002	Kinsella et al.
6,503,290	B1	1/2003	Jarosinski et al.
6,508,803	B1	1/2003	Horikawa et al.
6,592,570	B2	7/2003	Abrams et al.
6,599,415	B1	7/2003	Ku et al.
6,602,228	B2	8/2003	Nanis et al.
6,602,272	B2	8/2003	Boylan et al.
6,610,046	B1	8/2003	Usami et al.
6,620,192	B1	9/2003	Jalisi
6,679,980	B1	1/2004	Andreacchi
7,105,018	B1	9/2006	Yip et al.
7,156,869	B1	1/2007	Pacetti
7,208,070	B2	4/2007	Swain
7,244,319	B2	7/2007	Abrams et al.
7,250,058	B1	7/2007	Pacetti et al.
7,252,746	B2	8/2007	Schaeffer
7,294,214	B2	11/2007	Craig
7,318,837	B2	1/2008	Krivoruchko et al.
7,357,854	B1	4/2008	Andreacchi
7,413,574	B2	8/2008	Yip et al.
7,488,343	B2	2/2009	O'Brien et al.
7,494,474	B2	2/2009	Richardson et al.
7,498,062	B2	3/2009	Calcaterra et al.
7,501,048	B2	3/2009	Oermans et al.
7,540,997	B2	6/2009	Stinson
7,601,230	B2	10/2009	Craig
7,632,303	B1	12/2009	Stalker et al.
7,740,798	B2	6/2010	Stinson
7,771,581	B2	8/2010	Callol et al.
7,785,274	B2	8/2010	Mishima et al.
7,883,474	B1	2/2011	Mirigian et al.
8,100,837	B1	1/2012	Cornish et al.
8,267,872	B2	9/2012	Ressemann et al.
8,323,459	B2	12/2012	Andreacchi et al.
8,348,860	B2	1/2013	Murayama et al.
8,360,995	B2	1/2013	Elsesser et al.
8,430,923	B2	4/2013	Pacetti et al.
8,529,710	B2	9/2013	Ishida et al.
8,591,672	B2	11/2013	Janko et al.
8,790,393	B2	7/2014	Bregulla et al.
8,808,618	B2	8/2014	Furst et al.
8,815,061	B2	8/2014	Andreacchi et al.
8,852,264	B2	10/2014	Pacetti et al.
9,045,843	B2	6/2015	Andreacchi et al.
9,133,563	B2	9/2015	Andreacchi
9,145,619	B2	9/2015	Andreacchi et al.
9,566,147	B2	2/2017	Kramer-Brown et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

9,566,174	B1	2/2017	De et al.
9,592,135	B2	3/2017	Thompson
9,668,890	B2	6/2017	Ma et al.
10,441,445	B2	10/2019	Kramer-Brown et al.
10,617,541	B2	4/2020	Nishigishi
10,835,393	B2	11/2020	Ma et al.
11,141,296	B2	10/2021	Thompson
11,298,251	B2	4/2022	Simpson et al.
2001/0009981	A1	7/2001	DuBois et al.
2002/0032477	A1	3/2002	Helmus et al.
2002/0062092	A1	5/2002	Muni et al.
2002/0082524	A1	6/2002	Anderson et al.
2002/0087099	A1*	7/2002	Nanis A61L 31/022 600/585
2003/0102360	A1	6/2003	Eungard et al.
2003/0120181	A1	6/2003	Toma et al.
2003/0125642	A1	7/2003	Kato et al.
2003/0134142	A1	7/2003	Ivey et al.
2004/0111044	A1	6/2004	Davis et al.
2004/0129347	A1	7/2004	Craig
2004/0167436	A1	8/2004	Reynolds et al.
2004/0167442	A1	8/2004	Shireman et al.
2004/0181175	A1	9/2004	Clayman et al.
2004/0225231	A1	11/2004	Ehr
2004/0236433	A1	11/2004	Kennedy et al.
2004/0243168	A1	12/2004	Ferrera et al.
2004/0267351	A1	12/2004	Swain
2005/0054952	A1	3/2005	Eskuri et al.
2005/0056687	A1*	3/2005	Matsumoto H05K 3/3485 228/248.1
2005/0059889	A1	3/2005	Mayer
2005/0060025	A1	3/2005	Mackiewicz et al.
2005/0070997	A1	3/2005	Thornton et al.
2005/0096568	A1	5/2005	Kato
2005/0098444	A1	5/2005	Schaeffer
2005/0124917	A1	6/2005	Skujins et al.
2005/0137501	A1	6/2005	Euteneuer et al.
2005/0145307	A1	7/2005	Shireman et al.
2005/0145508	A1	7/2005	Arsen et al.
2005/0263171	A1	12/2005	Wu et al.
2005/0263717	A1	12/2005	Soluri et al.
2005/0267385	A1	12/2005	Hofmann et al.
2005/0273021	A1	12/2005	Burgermeister
2005/0273156	A1	12/2005	Burgermeister et al.
2005/0288773	A1	12/2005	Glocker et al.
2006/0079954	A1	4/2006	Burgermeister et al.
2006/0122537	A1	6/2006	Reynolds et al.
2006/0190070	A1	8/2006	Dieck et al.
2006/0241519	A1	10/2006	Hojeibane et al.
2006/0259126	A1	11/2006	Jason
2006/0264784	A1	11/2006	Lupton
2006/0271169	A1	11/2006	Ye et al.
2006/0272751	A1	12/2006	Kato
2006/0287709	A1	12/2006	Rao
2007/0034527	A1	2/2007	Diaz et al.
2007/0034528	A1	2/2007	Diaz et al.
2007/0135891	A1	6/2007	Schneider
2007/0156215	A1	7/2007	Jensen et al.
2007/0173925	A1	7/2007	Fliedner
2007/0185415	A1	8/2007	Ressemann et al.
2007/0185564	A1	8/2007	Pacetti et al.
2007/0198044	A1	8/2007	Lupton et al.
2007/0209947	A1	9/2007	Shrivastava et al.
2007/0219464	A1	9/2007	Davis et al.
2007/0219465	A1	9/2007	Cedro et al.
2007/0219624	A1	9/2007	Brown et al.
2007/0244413	A1	10/2007	Biggins
2007/0249964	A1	10/2007	Richardson et al.
2007/0249965	A1	10/2007	Abrams et al.
2007/0265699	A1	11/2007	Grewe et al.
2007/0270942	A1	11/2007	Thomas
2008/0004546	A1	1/2008	Kato
2008/0033522	A1	2/2008	Grewe et al.
2008/0070058	A1	3/2008	Dasgupta et al.
2008/0077049	A1	3/2008	Hirshman
2008/0091267	A1	4/2008	Stinson et al.
2008/0097248	A1	4/2008	Munoz et al.
2008/0146967	A1	6/2008	Richardson et al.
2008/0160259	A1	7/2008	Nielson et al.
2008/0161726	A1	7/2008	Itou
2008/0177371	A1	7/2008	Ryan et al.
2008/0183280	A1	7/2008	Agnew et al.
2008/0200879	A1	8/2008	Isi et al.
2008/0208308	A1	8/2008	Allen et al.
2008/0208352	A1	8/2008	Krivoruchko et al.
2008/0215132	A1	9/2008	Ryan et al.
2008/0228109	A1	9/2008	Kinoshita et al.
2008/0234605	A1	9/2008	Urie
2008/0257717	A1	10/2008	Vacheron
2008/0262600	A1	10/2008	Jalisi
2008/0281230	A1	11/2008	Kinoshita et al.
2008/0312747	A1	12/2008	Cameron et al.
2009/0000105	A1	1/2009	Kato
2009/0030500	A1	1/2009	Weber et al.
2009/0048659	A1	2/2009	Weber et al.
2009/0093871	A1	4/2009	Rea et al.
2009/0112127	A1	4/2009	Keating et al.
2009/0118675	A1	5/2009	Czyscon et al.
2009/0118822	A1	5/2009	Holman et al.
2009/0149947	A1	6/2009	Frohwitter
2009/0163833	A1	6/2009	Kinoshita et al.
2009/0204203	A1	8/2009	Allen et al.
2009/0227902	A1	9/2009	Simpson et al.
2009/0240324	A1	9/2009	Smith
2009/0254000	A1	10/2009	Layman et al.
2009/0255827	A1	10/2009	Andreacchi et al.
2009/0258050	A1	10/2009	Lindsay et al.
2009/0259299	A1	10/2009	Moloney
2009/0276033	A1	11/2009	Mayer
2010/0004562	A1	1/2010	Jalisi et al.
2010/0004733	A1	1/2010	Atanasoska et al.
2010/0049304	A1	2/2010	Clifford et al.
2010/0158426	A1	6/2010	Manipatruni et al.
2010/0158436	A1	6/2010	Riska
2010/0217373	A1	8/2010	Boyle et al.
2010/0222866	A1	9/2010	Wachter et al.
2010/0222873	A1	9/2010	Atanasoska et al.
2010/0241210	A1	9/2010	Patadia
2010/0249654	A1*	9/2010	Elsesser A61M 25/09 600/585
2010/0262227	A1	10/2010	Rangwala et al.
2011/0062031	A1	3/2011	Wulf
2011/0066106	A1	3/2011	Kato
2011/0106236	A1	5/2011	Su et al.
2011/0118628	A1	5/2011	Zhou et al.
2011/0247943	A1	10/2011	Bialas et al.
2011/0264161	A1	10/2011	Schiefer et al.
2011/0319872	A1	12/2011	Kawasaki
2011/0319980	A1	12/2011	Ryan
2012/0016458	A1	1/2012	Abunassar
2012/0041342	A1	2/2012	Purtzer
2012/0065623	A1	3/2012	Nelson, III et al.
2012/0109108	A1	5/2012	Boyle et al.
2012/0123525	A1	5/2012	Kramer-Brown et al.
2012/0199489	A1	8/2012	Vacheron
2012/0282571	A1*	11/2012	Ammon C21D 6/007 433/102
2013/0006149	A1	1/2013	Purtzer
2013/0006222	A1	1/2013	Nabeshima et al.
2013/0013055	A1	1/2013	Pacetti et al.
2013/0092554	A1	4/2013	Wong et al.
2013/0092556	A1	4/2013	Wong et al.
2013/0092557	A1	4/2013	Wong et al.
2013/0204353	A1	8/2013	Kramer-Brown et al.
2013/0241112	A1	9/2013	Jow
2014/0014530	A1	1/2014	Zhicheng
2014/0076719	A1	3/2014	Andreacchi et al.
2014/0076720	A1	3/2014	Andreacchi et al.
2014/0076737	A1	3/2014	Andreacchi et al.
2014/0076739	A1	3/2014	Andreacchi
2014/0155979	A1	6/2014	Am et al.
2014/0271319	A1	9/2014	Zheng et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2014/0360887 A1	12/2014	Andreacchi et al.
2016/0002816 A1	1/2016	Andreacchi
2017/0296365 A1	10/2017	Kramer-Brown et al.

FOREIGN PATENT DOCUMENTS

CN	102356185 A	2/2012
CN	102481662 A	5/2012
CN	102552991 A	7/2012
CN	202412010 U	9/2012
CN	103252496 A	8/2013
CN	110306099 A	10/2019
EP	0804934 A2	11/1997
EP	1604691 A2	12/2005
EP	1632584 A1	3/2006
EP	1674118 A2	6/2006
EP	1 731 241	12/2006
EP	1829982 A1	9/2007
EP	2054101 A2	5/2009
EP	2640432	5/2012
EP	2676684 A1	12/2013
EP	2676686 A1	12/2013
EP	3138587 A1	8/2017
JP	07-090694 A	4/1995
JP	08-302500 A	11/1996
JP	H09508538	9/1997
JP	2002503529	2/2002
JP	2002069555	3/2002
JP	2003267609	9/2003
JP	2006519068	8/2006
JP	2008188670	8/2008
WO	97/33534 A1	9/1997
WO	99/15108 A2	4/1999
WO	00/54704 A1	9/2000
WO	00/69368 A2	11/2000
WO	01/15632 A1	3/2001
WO	01/17577 A1	3/2001
WO	01/61080 A1	8/2001
WO	01/72349 A1	10/2001
WO	02/78763	10/2002
WO	2007/103446 A2	9/2007
WO	WO 2008/022126	2/2008
WO	2009/126431 A2	10/2009
WO	2010/081723 A1	7/2010
WO	WO 2010/107798	9/2010
WO	2012/068358 A1	5/2012
WO	2013/162690 A1	10/2013
WO	2014/159743 A1	10/2014
WO	2014/159747 A1	10/2014

OTHER PUBLICATIONS

Eutectic system. In *Wikipedia, The Free Encyclopedia*. Retrieved 11:54, Apr. 27, 2010, 1-5, from https://en.wikipedia.org/w/index.php?title=Eutectic_system&oldid=702728275.

Gold. In *Wikipedia, The Free Encyclopedia*. Revised on Apr. 22, 2010, Retrieved 11:11, Aug. 7, 2017, 1-21, from https://en.wikipedia.org/w/index.php?title=Gold&diff=357659233&oldid=357425502.

Indium. In *Wikipedia, The Free Encyclopedia*. Retrieved 12:13, Apr. 27, 2010, 1-7, from https://en.wikipedia.org/w/index.php?title=lndium&oldid=706790732.

Jacobson, D. M., & Humpston, G. (1989). Gold coatings for fluxless soldering. *Gold Bulletin*, 22(1), 9-18.

Tin. In *Wikipedia, The Free Encyclopedia*. Retrieved 12:08, Apr. 27, 2010, 1-15, from https://en.wikipedia.org/w/index.php?title=Tin&oldid=708568728.

U.S. Appl. No. 13/172,278, filed Jun. 10, 2013 Office Action.

U.S. Appl. No. 13/172,278, filed Nov. 21, 2013 Office Action.

U.S. Appl. No. 13/172,278, filed Apr. 3, 2015 Office Action.

U.S. Appl. No. 13/172,278, filed Oct. 8, 2015 Office Action.

U.S. Appl. No. 13/172,278, filed Sep. 19, 2016 Office Action.

U.S. Appl. No. 13/172,278, filed Apr. 11, 2017 Notice of Allowance.

U.S. Appl. No. 13/172,278, filed Jul. 19, 2017 Issue Notification.

Narushima, Precipitates-in-Biomedical-Co-Cr-Alloys_Narushima-Mineta-Kurihara-Ueda_Publishedonline-February26,2013, Feb. 26, 2013, JOM, Vol. 65, No. 4, 2013, 489, 65.

Campbell, ed. Chapter 16 Nonequilbrium Reactions-Precipitation Hardening. Phase Diagrams Understanding the Basics. ASM International. 2012. 339-361. (Year: 2012).

CN 101554685 machine translation (Year: 2009).

CN 103252496 machine translation (Year: 2013).

CN 110306099 machine translation (Year: 2019).

Cordis Palmaz Blue 018 Peripheral Stent System, Johson & Johnson Medical NV/SA, May 2005 (2 pages) http://www.jjnordic.com/Lists/FileList1/Attatchments/174/PalmazBlue.sub .- - 018.sub .-Brochure.PDF.

Dinega, Dmitry P., and M. G. Bawendi. "A solution-phase chemical approach to a new crystal structure of cobalt." Angewandte Chemie International Edition 38.12 (1999): 1788-1791.

Donachie et al. Chapter 7 Powder Metallurgy Processing. Superalloys A Technical Guide. Second Edition. 2002. ASM International. 117-134. (Year: 2002).

Final Office Action received for U.S. Appl. No. 16/601,259, dated Sep. 23, 2021, 11 pages.

Forging of Niobium, tantalum, and their alloys, MetalPass, accessed Apr. 18, 2013. http://www.metalpass.com/metaldoc/paper.aspx?docID=312.

Giessen et al., "Coronary Stenting with a New Radiopaque Balloon Expandable Endoprosthesis in Pigs", Circulation, vol. 83, No. 5, May 1991, pp. 1788-1798.

International Search Report and Written Opinion of the International Searching Authority dated Sep. 26, 2007, for related PCT Application No. PCT/US2007/05844.

Issue Notification received for U.S. Appl. No. 09/534,071, mailed on Jul. 11, 2007.

Issue Notification received for U.S. Appl. No. 13/548,908 mailed on Mar. 11, 2015.

Issue Notification received for U.S. Appl. No. 13/618,602, mailed on Sep. 17, 2014.

Liu. 2 Processes and Techniques for Droplet Generation. Science and Engineering of Droplets. Notes Publications. 2000. 19-120. (Year: 2000).

Non-Final Office Action received for U.S. Appl. No. 16/601,259, dated May 17, 2021, 11 pages.

Non-Final Office Action received for U.S. Appl. No. 17/068,526, mailed on Oct. 5, 2022, 35 pages.

Notice of Allowance received for U.S. Appl. No. 09/534,071, mailed on Feb. 12, 2007.

Notice of Allowance received for U.S. Appl. No. 11/736,979, mailed on Nov. 9, 2012.

Notice of Allowance received for U.S. Appl. No. 12/100,991 mailed on Aug. 17, 2012.

Notice of Allowance received for U.S. Appl. No. 13/548,908 mailed on Dec. 2, 2014.

Notice of Allowance received for U.S. Appl. No. 13/617,877, mailed on May 28, 2015.

Notice of Allowance received for U.S. Appl. No. 13/618,348 mailed on Aug. 6, 2014.

Notice of Allowance received for U.S. Appl. No. 13/618,455, mailed on Feb. 2, 2015.

Notice of Allowance received for U.S. Appl. No. 14/466,513, mailed on Mar. 28, 2017.

Notice of Allowance received for U.S. Appl. No. 16/601,259, mailed on Dec. 6, 2021, 8 pages.

Notice of Allowance received for U.S. Appl. No. 16/601,259, mailed on Mar. 9, 2022, 6 pages.

Notice of Allowance received for U.S. Appl. No. 11/370,642 mailed on Apr. 12, 2010.

Notice of Allowance received for U.S. Appl. No. 13/618,602, mailed on May 27, 2014.

Notice of Allowance received for U.S. Appl. No. 13/830,404, mailed on Oct. 18, 2016.

Notice of Allowance received for U.S. Appl. No. 15/429,339, mailed on Jun. 5, 2019.

(56) **References Cited**

OTHER PUBLICATIONS

Notification of Transmittal of the International Search Report and the Written Opinion of the International Searching Authority, or the Declaration, Patent Cooperation Treaty, European Patent Office, Dec. 29, 2009 (12 pages).
Office Action received for U.S. Appl. No. 09/534,071, dated Aug. 29, 2005.
Office Action received for U.S. Appl. No. 09/534,071, dated Dec. 18, 2002.
Office Action received for U.S. Appl. No. 09/534,071, dated Mar. 13, 2006.
Office Action received for U.S. Appl. No. 09/534,071, dated Nov. 15, 2005.
Office Action received for U.S. Appl. No. 09/534,071, dated Sep. 13, 2006.
Office Action received for U.S. Appl. No. 09/534,071, dated Sep. 17, 2002.
Office Action received for U.S. Appl. No. 11/370,642 dated Sep. 22, 2009.
Office Action received for U.S. Appl. No. 11/736,979, dated Apr. 4, 2011.
Office Action received for U.S. Appl. No. 11/736,979, dated Apr. 12, 2012.
Office Action received for U.S. Appl. No. 11/736,979, dated Aug. 31, 2010.
Office Action received for U.S. Appl. No. 11/736,979, dated May 26, 2010.
Office Action received for U.S. Appl. No. 11/736,979, dated Sep. 19, 2011.
Office Action received for U.S. Appl. No. 12/100,991 dated Dec. 21, 2011.
Office Action received for U.S. Appl. No. 12/100,991 dated Sep. 29, 2011.
Office Action received for U.S. Appl. No. 13/271,869 dated Apr. 26, 2013.
Office Action received for U.S. Appl. No. 13/271,869 dated Nov. 27, 2013.
Office Action received for U.S. Appl. No. 13/548,908 dated Jun. 18, 2014.
Office Action received for U.S. Appl. No. 13/618,407, dated Dec. 2, 2014.
Office Action received for U.S. Appl. No. 13/618,455 dated May 8, 2014.
Office Action received for U.S. Appl. No. 13/618,455 dated Sep. 25, 2014.
Office Action received for U.S. Appl. No. 13/618,602, dated May 3, 2013.
Office Action received for U.S. Appl. No. 09/534,071, dated Jul. 9, 2003.
Office Action received for U.S. Appl. No. 13/298,070, dated Jun. 25, 2014.
Office Action received for U.S. Appl. No. 13/298,070, dated Oct. 6, 2014.
Office Action received for U.S. Appl. No. 13/618,602, dated Aug. 20, 2013.
Office Action received for U.S. Appl. No. 13/618,602, dated Jan. 6, 2014.
Office Action received for U.S. Appl. No. 13/830,404, dated Apr. 20, 2016.
Office Action received for U.S. Appl. No. 13/830,404, dated Aug. 10, 2016.
Office Action received for U.S. Appl. No. 13/830,404, dated Jan. 8, 2016.
Office Action received for U.S. Appl. No. 13/830,404, dated May 29, 2015.
Office Action received for U.S. Appl. No. 13/830,404, dated Sep. 16, 2015.
Office Action received for U.S. Appl. No. 15/429,339, dated Feb. 26, 2019.
Ohring et al. "A Versatile Arc Melting Apparatus for Quenching Molten Metals and Ceramics." Review of Scientific instruments 42.4 (1971): 530-531.
Poletti et al. Development of a new high entropy alloy for wear resistance: FeCoCrNiWO.3 and FeCoCrNiW0.3+5 at% of C. Materials and Design 115 (2017) 247-254. (Year: 2017).
Restriction Requirement received for U.S. Appl. No. 13/618,602, mailed on Mar. 4, 2013.
Restriction Requirement received for U.S. Appl. No. 17/068,526, mailed on Jul. 15, 2022, 6 pages.
Restriction Requirement received for U.S. Appl. No. 13/298,070, mailed on May 2, 2014.
Shang. CoCrFeNi(W1-xMox) high-entropy alloy coatings with excellent mechanical properties and corrosion resistance prepared by mechanical alloying and hot pressing sintering. Materials and Design 117 (2017) 193-202. (Year: 2017).
Sheng. A Co-Cr-Ni-W-C alloy processed by multiple rolling. Strength of Materials, vol. 52, No. 1, Jan. 2020. (Year: 2020).
Tanaka. Effects of high-temperature ageing on the creep-rupture properties of high-tungsten cobalt-base superalloys. Journal of Materials Science 29 (1994) 2620-2628. (Year: 1994).
U.S. Appl. No. 11/370,642, filed Apr. 12, 2010, Notice of Allowance.
U.S. Appl. No. 11/370,642, filed Sep. 22, 2009, Office Action.
U.S. Appl. No. 11/736,979, filed Apr. 10, 2013, Issue Notification.
U.S. Appl. No. 13/271,869, filed Apr. 1, 2013, Office Action.
U.S. Appl. No. 13/271,869, filed Apr. 26, 2013, Office Action.
U.S. Appl. No. 13/271,869, filed Jul. 9, 2014, Issue Notification.
U.S. Appl. No. 13/271,869, filed Mar. 18, 2014, Notice of Allowance.
U.S. Appl. No. 13/271,869, filed Nov. 27, 2013, Office Action.
U.S. Appl. No. 13/617,877, filed Dec. 20, 2013, Office Action.
U.S. Appl. No. 13/617,877, filed Sep. 23, 2014, Office Action.
U.S. Appl. No. 13/618,348, filed Dec. 19, 2013, Office Action.
U.S. Appl. No. 13/618,348, filed Sep. 14, 2012, Anthony S. Andreacchi, Aug. 6, 2014, Issue Notification.
U.S. Appl. No. 13/618,348, Mail Date Apr. 16, 2014, Notice of Allowance.
U.S. Appl. No. 13/618,407, Mail Date May 13, 2015, Notice of Allowance.
U.S. Appl. No. 13/618,455, filed Sep. 14, 2012, Andreacchi et al.
U.S. Appl. No. 13/618,455, Mail Date May 13, 2015, Issue Notification.
U.S. Appl. No. 11/736,979, filed Feb. 20, 2013, Issue Notification.
Wang et al. Microstructure and mechanical properties of CoCrFeNiWx high entropy alloys reinforced by u phase particles. Journal of Alloys and Compounds 843 (2020) 155997. (Year: 2020).
Zhang et al. Phase transformations in Co-Ni-Cr-W alloys during high temperature exposure to steam environment. J. Phase Equil. Diffus. (2018) 39:387-400. (Year: 2018).

* cited by examiner

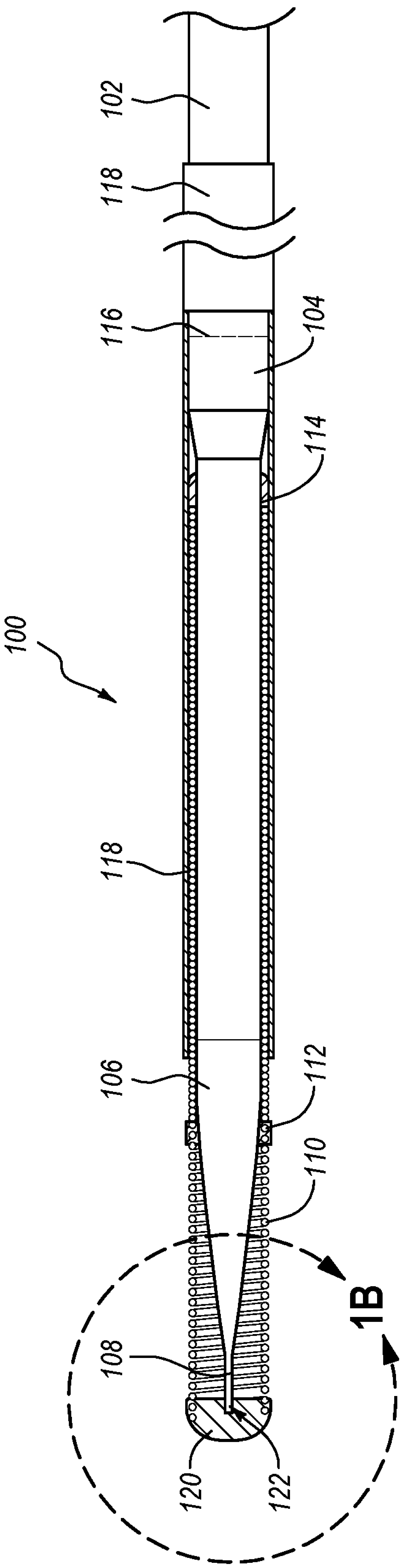


Fig. 1A

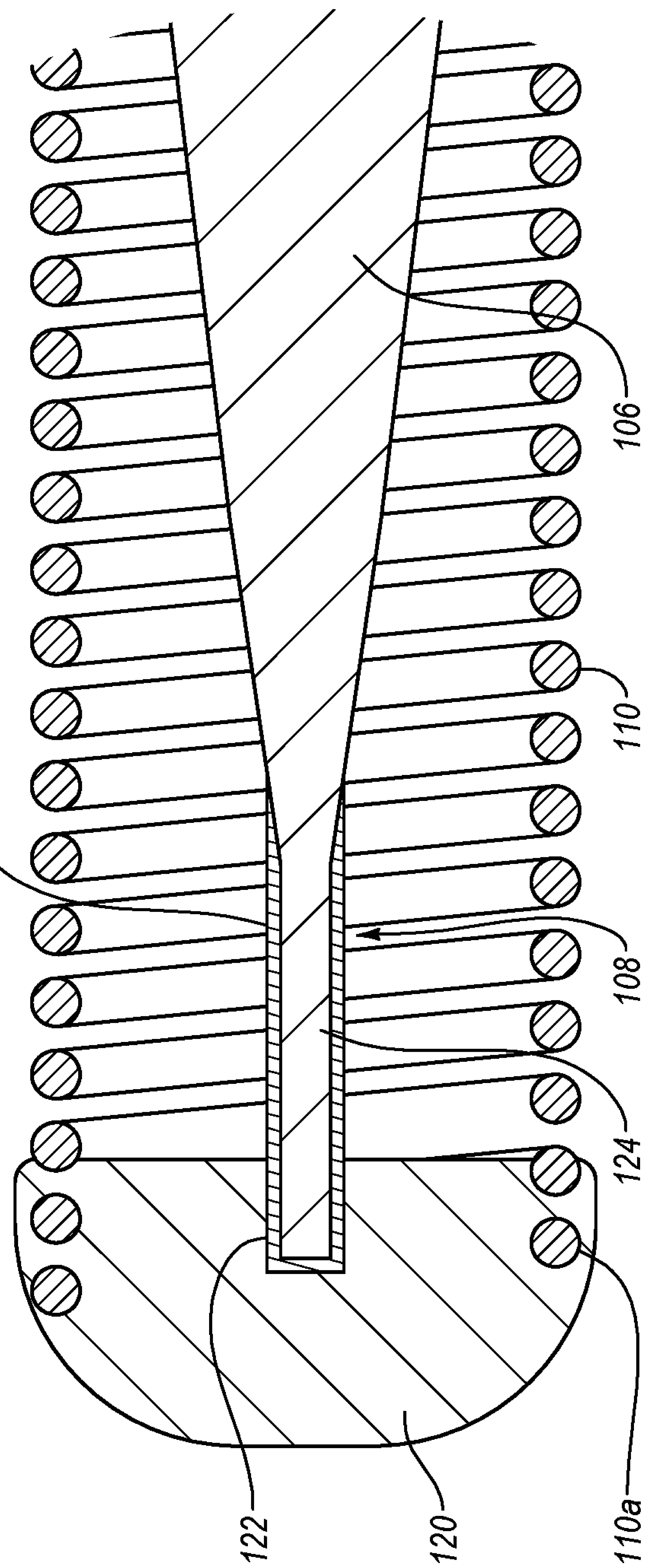


Fig. 1B

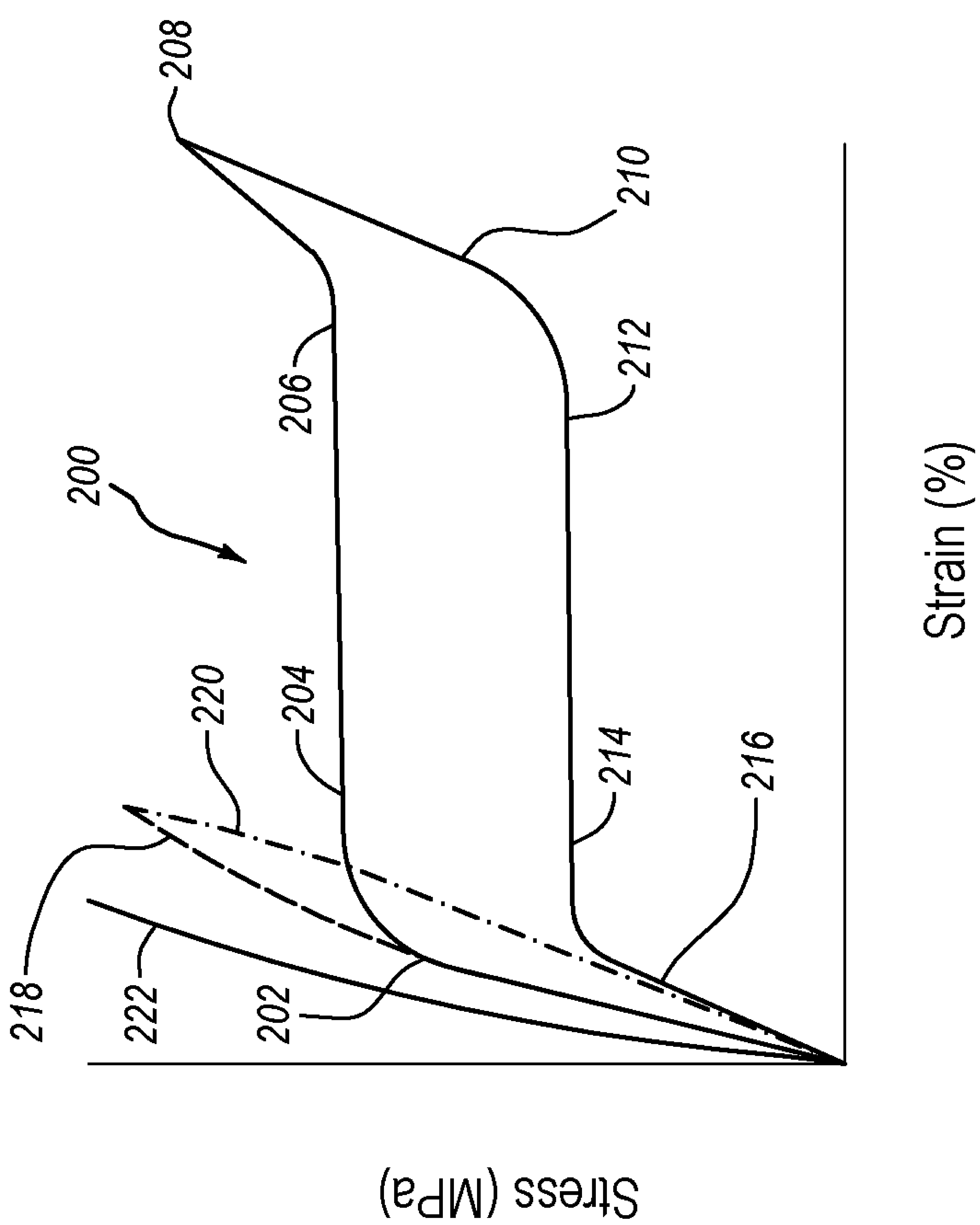
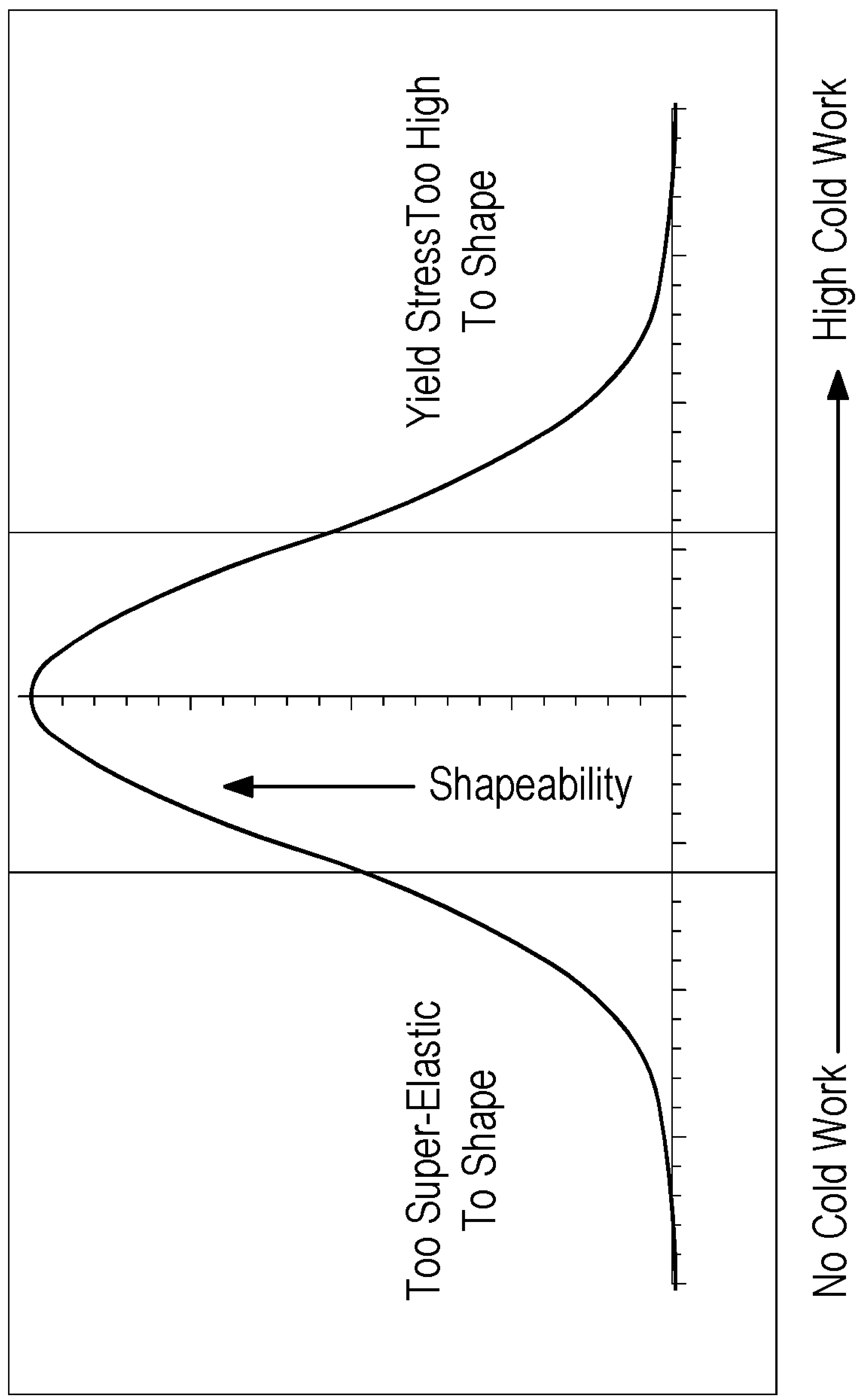

200
202
204
206
208
210
212
214
216
218
220
222
Strain (%)
Stress (MPa)

Fig. 2



Yield StressToo High
To Shape
Shapeability
Too Super-Elastic
To Shape
No Cold Work
High Cold Work

Fig. 3

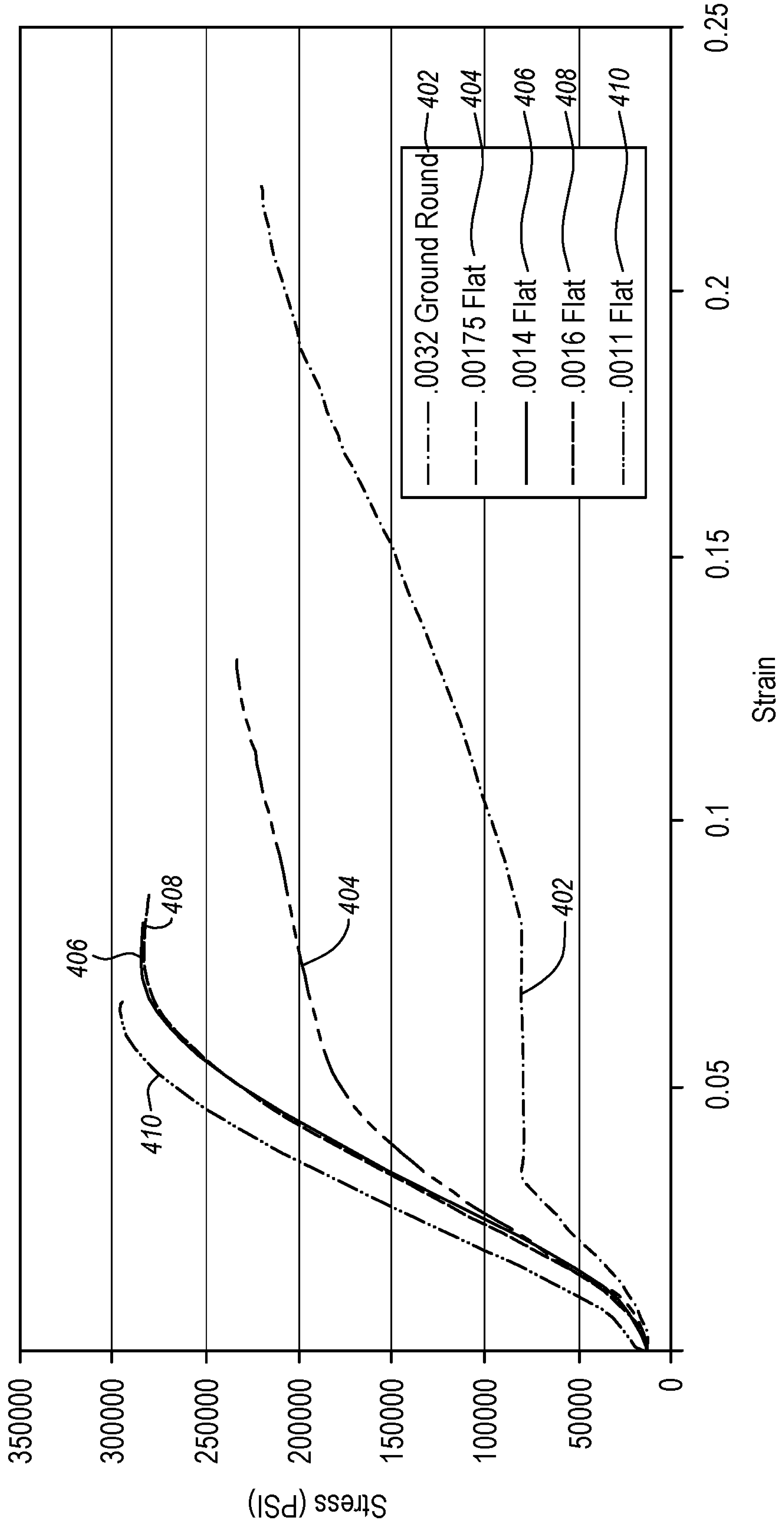

Stress (PSI)
350000
300000
250000
200000
150000
100000
50000
0
Strain
0
0.05
0.1
0.15
0.2
0.25
.0032 Ground Round
.00175 Flat
.0014 Flat
.0016 Flat
.0011 Flat
402
404
406
408
410

Fig. 4

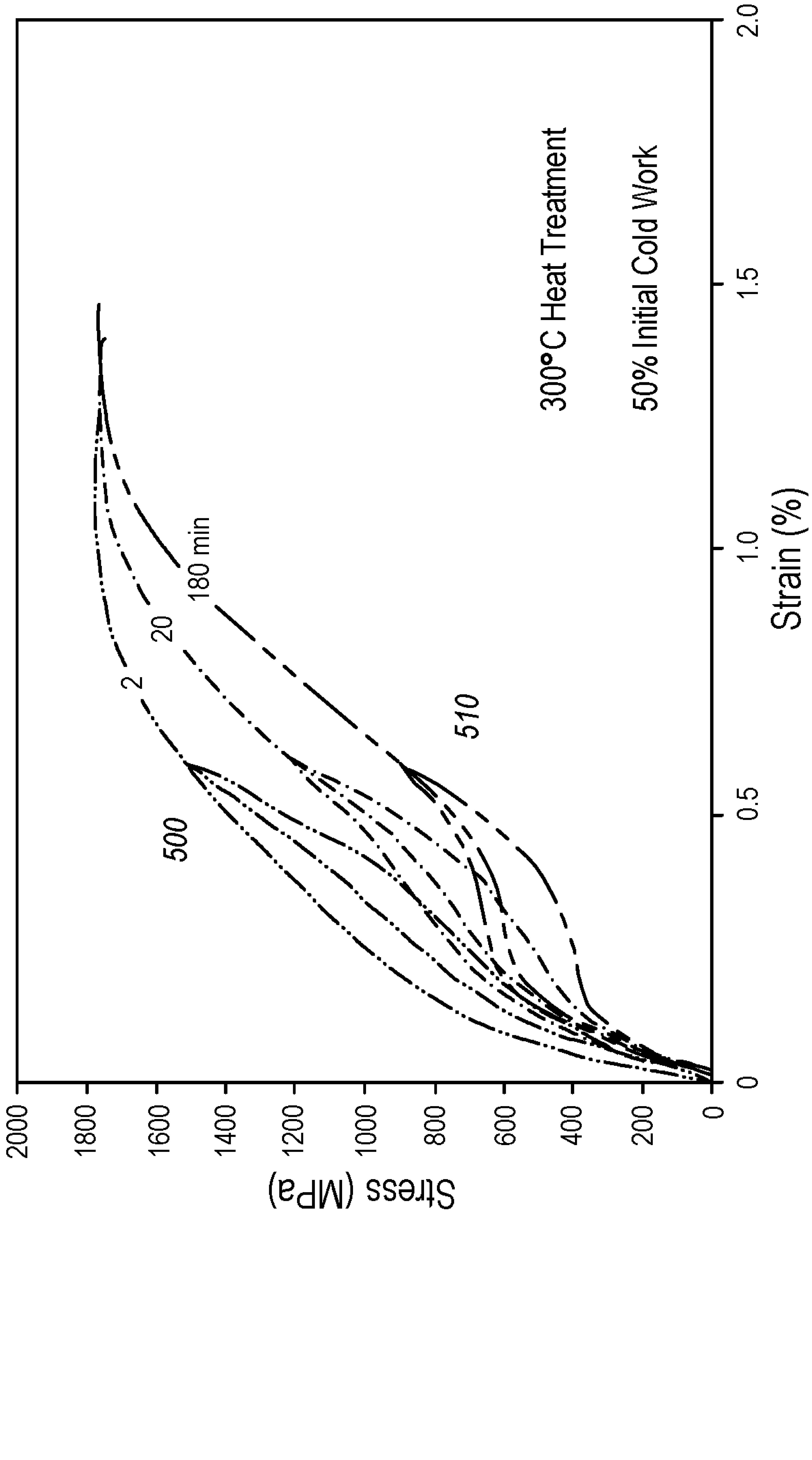

Stress (MPa)
Strain (%)
300°C Heat Treatment
50% Initial Cold Work
180 min
20
2
500
510
0
200
400
600
800
1000
1200
1400
1600
1800
2000
0
0.5
1.0
1.5
2.0

Fig. 5

MEDICAL DEVICE INCLUDING A SOLDERABLE LINEAR ELASTIC NICKEL-TITANIUM DISTAL END SECTION AND METHODS OF PREPARATION THEREFOR

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 13/172,278, filed 29 Jun. 2011, the disclosure of which is incorporated herein by reference in its entirety.

BACKGROUND

1. The Field of the Invention

The present invention relates to guide wires, particularly to guide wires used to guide a catheter in a body lumen such as a blood vessel.

2. The Relevant Technology

Guide wires are used to guide a catheter for treatment of intravascular sites, such as percutaneous transluminal coronary angioplasty ("PTCA"), or in examination such as cardio-angiography. A guide wire used in the PTCA is inserted into the vicinity of a target angiostenosis portion together with a balloon catheter, and is operated to guide the distal end portion of the balloon catheter to the target angiostenosis portion.

A guide wire needs appropriate flexibility, pushability and torque transmission performance for transmitting an operational force from the proximal end portion to the distal end, and kink resistance (resistance against sharp bending). To meet such requirements, superelastic materials such as a Ni—Ti alloy and high strength materials have been used for forming a core member (i.e., a wire body) of a guide wire.

Near equiatomic binary nickel-titanium alloys are known to exhibit "pseudoelastic" behavior when given certain cold working processes or cold working and heat treatment processes following hot working. Pseudoelasticity can be further divided into two subcategories: "linear" pseudoelasticity and "non-linear" pseudoelasticity. "Non-linear" pseudoelasticity is sometimes used by those in the industry synonymously with "superelasticity."

Linear pseudoelasticity typically results from cold working. Non-linear pseudoelasticity results from cold working and subsequent heat treatment. Non-linear pseudoelasticity, in its idealized state, exhibits a relatively flat loading plateau in which a large amount of recoverable strain is possible with very little increase in stress. This flat plateau can be seen in the stress-strain hysteresis curve of the alloy. Linear pseudoelasticity exhibits no such flat plateau. Non-linear pseudoelasticity is known to occur due to a reversible phase transformation from austenite to martensite, the latter more precisely called stress-induced martensite ("SIM"). Linear pseudoelastic materials exhibit no such phase transformation. Linear pseudoelastic nickel titanium alloy can be permanently deformed or shaped by overstressing the alloy above a plateau stress that is at least partially dependent on the amount of cold-worked martensite structure present in the linear pseudoelastic structure. This is in marked contrast to non-linear pseudoelastic nickel titanium alloy, which cannot be permanently deformed by overstressing.

BRIEF SUMMARY

The present disclosure describes guide wire devices and methods for their manufacture. Guide wire devices described herein include an elongate shaft member having a shapeable distal end section that is formed from a linear pseudoelastic nickel-titanium (Ni—Ti) alloy that has linear pseudoelastic behavior without a phase transformation or onset of stress-induced martensite. Linear pseudoelastic Ni—Ti alloy, which is distinct from non-linear pseudoelastic (i.e., superelastic) Ni—Ti alloy, is highly durable, corrosion resistant, and has high stiffness. The shapeable distal end section is shapeable by a user to facilitate guiding the guide wire through tortuous anatomy. In addition, linear pseudoelastic Ni—Ti alloy is more durable tip material than other shapeable tip materials such as stainless steel. This may, for example, allow practitioners to use one wire to treat multiple lesions, potentially reducing costs and procedure time.

In one embodiment, a shapeable guide wire device is described. The shapeable guide wire device includes an elongate shaft member that includes a proximal end section and a shapeable distal end section having a solder material applied thereto, wherein the shapeable distal end section includes a cold-worked nickel titanium alloy exhibiting linear pseudoelasticity. The shapeable guide wire device further includes a helical coil section disposed about at least the shapeable distal end section and an atraumatic cap section attached to the helical coil section and the solder material of the shapeable distal end section via a soldered joint. According to the present disclosure, the soldered joint is formed without substantial loss of the linear pseudoelasticity of the shapeable distal end section.

In another embodiment, a method for fabricating a guide wire device is disclosed. The method includes (1) fabricating an elongate shaft member that includes a proximal end section and a distal end section. In one embodiment, the distal end section includes a distal nickel-titanium alloy member that has a first cross-sectional dimension. The method further includes (2) applying a solder material to at least a portion of the distal end section, (3) cold working at least a portion of the distal end section having the solder material applied thereto, wherein the cold working yields a distal shapeable end section having a second cross-sectional dimension and linear pseudoelastic deformation behavior, and (4) soldering the distal shapeable section and a helical coil section disposed about the distal shapeable section to an atraumatic cap without substantial loss of the linear pseudoelasticity of the distal shapeable section.

In one embodiment, fabricating an elongate shaft member that includes a proximal end section and a distal end section may include attaching (e.g., by welding) a proximal end section fabricated from a first material such as stainless steel to a distal end section fabricated from a second material such as nickel-titanium alloy. Alternatively, the elongate shaft member can be fabricated from a single material such as, but not limited to, a nickel-titanium alloy.

In one embodiment, fabricating an elongate shaft member may further include drawing at least a portion of the elongate shaft member through a drawing die, rolling, calendaring, or grinding to form or reshape the at least a portion of the elongate shaft member and cleaning the elongate shaft member such as by ultrasonically cleaning.

Ni—Ti alloys, such as those described herein, are very difficult to solder due to the formation of a tenacious, naturally occurring oxide coating which prevents the molten solder from wetting the surface of the alloy. It has been found that by first treating the surface of the refractory superelastic alloy with molten alkali metal hydroxide, e.g., sodium, potassium, lithium or mixtures thereof to form a nascent alloy surface and then pretinning (i.e., applying a suitable solder material, such as, a gold-tin solder, a gold-indium solder, a gold-germanium solder, a silver-tin solder, a silver-gold-tin solder, or another suitable solder) without contacting air, that Ni—Ti alloys can be readily soldered in a conventional manner. In one embodiment, solder can be applied to at least a portion of the distal end section by dipping the at least the distal end section into a bath of a molten solder material, wherein the bath of molten solder material includes an upper layer of a molten metal hydroxide and a lower layer of the molten solder material.

Subsequently, at least a portion of the distal end section, with the solder material applied thereto, can be cold-worked to yield a distal shapeable end section having a second cross-sectional dimension. After applying the solder material and cold working, a helical coil section can be assembled around the a distal portion of the elongate shaft member, including the distal shapeable section, and a rounded plug (i.e., an aturaumatic cap section) can be formed at the distal end of the assembly by soldering the distal shapeable section and a helical coil section disposed about the distal shapeable section to the rounded plug without substantial loss of the linear pseudoelasticity of the distal shapeable section. The pretinning followed by cold working and forming the atraumatic cap at the distal end of the elongate shaft member yields a user-shapeable distal end section that exhibits linear pseudoelastic deformation behavior without a phase transformation or onset of stress-induced martensite.

In a more specific embodiment, a method for fabricating a guide wire device that has a shapeable distal end section is disclosed. The method includes (1) providing an elongate shaft member that includes a proximal end section and a distal end section, wherein the distal end section includes a nickel-titanium alloy member, (2) grinding at least a portion of the distal end section to a first cross-sectional dimension, and (3) ultrasonically cleaning at least the distal end section. After grinding and cleaning, the method further includes (4) dipping at least a portion of the distal end section into a bath of a molten solder material, wherein the bath of molten solder material includes an upper layer of a molten metal hydroxide and a lower layer of the molten solder material, and (5) cold working at least a portion of the distal end section, wherein the cold working yields a distal shapeable section having a linear pseudoelastic nickel-titanium microstructure. After cold working at least a portion of the distal end section, the method continues with (6) ultrasonically cleaning at least the distal end section, (7) disposing a helical coil section about the distal shapeable section, and (8) forming an atraumatic cap section coupling the helical coil section and the distal shapeable section via a soldered joint, wherein the soldered joint is formed without loss of the linear elastic nickel-titanium microstructure.

These and other objects and features of the present disclosure will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

To further clarify the above and other advantages and features of the present disclosure, a more particular description of the embodiments of the invention will be rendered by reference to the appended drawings. It is appreciated that these drawings depict only illustrated embodiments of the invention and are therefore not to be considered limiting of its scope. The embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIG. **1**A illustrates a partial cut-away view of a guide wire device according to one embodiment of the present invention;

FIG. **1**B illustrates an enlarged view of a distal end portion of the guide wire device illustrated in FIG. **1**A;

FIG. **2** illustrates stress-strain curves for stainless steel, a linear pseudoelastic Ni—Ti alloy, and a superelastic (i.e., non-linear pseudoelastic) Ni—Ti alloy;

FIG. **3** is a diagram schematically illustrating the relationship between degree of cold work and shapeability of a Ni—Ti alloy;

FIG. **4** is a diagram illustrating the yield stress of samples of Ni—Ti alloy having various degrees of cold work; and

FIG. **5** is a diagram illustrating loss of linear pseudoelastic character of Ni—Ti alloy as a result of moderate heat exposure for varying amounts of time.

DETAILED DESCRIPTION

I. Introduction

The present disclosure describes guide wire devices and methods for their manufacture. Guide wire devices disclosed herein include an elongate shaft member having a shapeable distal end section that is formed from a linear pseudoelastic nickel-titanium (Ni—Ti) alloy that has linear pseudoelastic behavior without the onset of stress-induced martensite during deformation. Linear pseudoelastic Ni—Ti alloy, which is distinct from non-linear pseudoelastic (i.e., superelastic) Ni—Ti alloy, is highly durable, corrosion resistant, and has a relatively high stiffness. Linear pseudoelastic Ni—Ti is in the martensite phase at body temperature (e.g., about 37° C.); in contrast, superelastic Ni—Ti used for medical devices is typically manufactured in the austenite phase at body temperature and superelastic Ni—Ti experiences an austenite to martensite phase transformation when stressed. The shapeable distal end section is shapeable by a user to facilitate guiding the guide wire through tortuous anatomy. In addition, linear pseudoelastic Ni—Ti alloy is more durable tip material than other shapeable tip materials, such as stainless steel. This may, for example, allow practitioners to use one wire to treat multiple lesions, potentially reducing costs and procedure time.

Guide wire devices are used in minimal invasive procedures such as, but not limited to, percutaneous transluminal coronary angioplasty (PTCA) to track through vessels, access and cross lesions, and support interventional devices for a variety of procedures. Because they are designed to track through a patient's vasculature, for example, guide wire devices may be quite long (e.g., about 150 cm to about 300 cm in length) and thin. Guide wire devices need to be long enough to travel from an access point outside a patient's body to a treatment site and narrow enough to pass freely through the patient's vasculature. For example, a typical guide wire device has an overall diameter of about 0.2 mm to about 0.5 mm for coronary use (e.g., about the diameter of the pencil leads typically used in automatic pencils). Larger diameter guide wires may be employed in peripheral arteries and other body lumens. The diameter of the guide wire device affects its flexibility, support, and torque. Thinner wires are more flexible and are able to access narrower vessels while larger diameter wires offer greater support and torque transmission.

II. Guide Wire Devices

In one embodiment of the present invention, a shapeable guide wire device is described. The shapeable guide wire device includes an elongate shaft member that includes a proximal end section and a shapeable distal end section having a solder material applied thereto. The shapeable distal end section includes a cold-worked linear nickel-titanium alloy exhibiting linear pseudoelastic deformation behavior imparted by cold work. The shapeable guide wire device further includes a helical coil section disposed about at least the shapeable distal end section, and an atraumatic cap section that is attached to (e.g., soldered to) the helical coil section and the shapeable distal end section. The atraumatic cap section may be formed from a bead of solder material that is applied to the helical coil section and the shapeable distal end section. According to the present embodiment, the atraumatic cap section is attached to the helical coil and the distal end section without loss of the linear elastic nickel-titanium microstructure.

Referring now to FIG. **1**A, a partial cut-away view of a guide wire device **100** according to an embodiment of the invention is illustrated. The guide wire device **100** may be adapted to be inserted into a patient's body lumen, such as an artery. The guide wire device **100** includes an elongated proximal portion **102** and a distal portion **104**. In one embodiment, the elongated proximal portion **102** may be formed from a first material such as stainless steel (e.g., 316L stainless steel) or a Ni—Ti alloy and the distal portion may be formed from a second material such as a Ni—Ti alloy. In another embodiment, the elongated proximal portion **102** and the distal portion **104** may be formed from a single material, such as a Ni—Ti alloy. If the elongated proximal portion **102** and the distal portion **104** are formed from different materials, the elongated proximal portion **102** and the distal portion **104** may coupled to one another via a welded joint **116** or another joint such as an adhesive joint, a brazed joint, or another suitable joint that couples the proximal portion **102** and the distal portion **104** into a torque transmitting relationship.

The distal portion **104** has at least one tapered section **106** that becomes smaller in diameter in the distal direction. The length and diameter of the tapered distal core section **106** can, for example, affect the trackability of the guide wire device **100**. Typically, gradual or long tapers produce a guide wire device with less support but greater trackability, while abrupt or short tapers produce a guide wire device that provides greater support but also greater tendency to prolapse (i.e., kink) when steering.

The tapered distal core section **106** further includes a shapeable distal end section **108** that is formed from a Ni—Ti alloy in a linear pseudoelastic state. As will be discussed in greater detail below, the linear pseudoelastic state can be imparted upon Ni—Ti alloy by cold work. With increasing cold work, the elastic modulus of the linear section of the stress-strain curve increases, imparting different degrees of linear pseudoelasticity. Linear pseudoelastic Ni—Ti can readily be permanently deformed by stressing the material beyond its elastic strain limit. As such, the shapeable distal end section **108** can allow a practitioner to shape the distal and of the guide wire device **100** to a desired shape (e.g., a J-bend) for tracking through the patient's vasculature.

The Ni—Ti alloy portion(s) of the guide wire device **100** discussed herein, e.g., the distal portion **104**, are, in some embodiment, made of an alloy material that includes about 30 to about 52% titanium and a balance nickel. The alloy may also include up to about 10% of one or more other alloying elements. The other alloying elements may be selected from the group consisting of iron, cobalt, vanadium, platinum, palladium and copper. The alloy can contain up to about 10% copper and vanadium and up to 3% of the other alloying elements. Cold worked Ni—Ti alloy portions (e.g., the shapeable distal end section **108**) exhibit linear pseudoelastic behavior that is in the martensite phase without the appearance of stress-induced martensite upon deformation.

In one embodiment, the shapeable distal end section **108** is manufactured by, for example, drawing and grinding the distal end of the Ni—Ti distal section **104** to a first cross-sectional dimension, applying a solder material to the distal section **104**, and cold-working (e.g., by flattening) the ground portion to a second cross-sectional dimension. In another embodiment, the shapeable distal end section **108** is manufactured by, for example, drawing and grinding the distal end of the Ni—Ti distal section **104** to a first cross-sectional dimension (e.g., a thickness or a diameter), cold-working a first time, applying a solder material to the distal section **104**, and cold-working a second time (e.g., by flattening) the ground portion to a second cross-sectional dimension (e.g., a thickness). If cold working is performed prior to applying the solder material, it may be desirable to use a solder material with a sufficiently low melting temperature (e.g., as low as about 150° C.) such that a minimal amount of cold work is lost due to exposure to the molten solder.

The first dimension can be in a range from about 0.1 mm to about 0.07 mm, or about 0.08 mm. The second cross-sectional dimension, which is formed by, for example, cold-work flattening at least a part of the ground distal section, is in a range from about 0.065 mm to about 0.008 mm, about 0.055 mm to about 0.03 mm, about 0.05 to about 0.04 mm, or about 0.045 mm. In other words, the shapeable distal end section **108** is made from a Ni—Ti alloy that exhibits linear pseudoelastic deformation behavior imparted by about 20% to about 90% cold work, about 25% to about 65% cold work, about 40% cold work to about 50% cold work, or about 45% cold work.

The length of the shapeable distal end section **108** can, for example, affect the steerability of the guide-wire device **100**. In one embodiment, the shapeable distal end section **108** is about 1 cm to about 10 cm in length, about 2 cm to about 6 cm in length, about 2 cm to about 4 cm in length, or about 2 cm in length.

As illustrated in FIG. **1**A, the guide wire device **100** includes a helical coil section **110**. The helical coil section **110** affects support, trackability, and visibility of the guide wire device and provides tactile feedback. In some embodiments, the most distal section of the helical coil section **110** is made of radiopaque metal, such as platinum or platinum-nickel alloys, to facilitate the observation thereof while it is disposed within a patient's body. The helical coil section **110** is disposed about all or only a portion of the distal portion **104** and the shapeable distal end section **108**, and has a rounded, atraumatic cap section **120** on the distal end thereof. In some embodiments, the atraumatic cap section **120** is formed from a bead of solder applied to the helical coil section **110** and the shapeable distal end section **108**. Typical solder materials that can be used for forming the atraumatic cap section **120** include 80/20 gold-tin or 95/5 silver-tin. However, other suitable types of medical-grade, lead-free solder can be used. The helical coil section **110** is secured to the distal portion **104** at proximal location **114** and at intermediate location **112** by a suitable solder material and/or a suitable adhesive.

Referring now to FIG. **1**B, a cut-away view of an enlarged portion of the distal end of the guide wire device **100** is illustrated. The portion of the guide wire device **100** illustrated in FIG. **1**B shows the tapered distal section **106**, the shapeable distal end section **108**, the helical coil section **110**, and the atraumatic cap **120**. The shapeable distal end section **108** includes a distal wire portion **124** composed of a Ni—Ti alloy that extends from the tapered distal section **106**. As illustrated, the distal wire portion is coated with a layer of solder material **126** (e.g., a gold-tin solder, a gold-indium solder, a gold-germanium solder, a silver-tin solder, a silver-gold-tin solder, or another suitable solder). At least a portion of the distal wire portion **124** is cold worked after application of the layer of solder material **126** in order to form the shapeable distal end section **108**.

The helical coil section **110** is attached to the shapeable distal end section **108** by soldering the rounded, atraumatic cap section **120** onto the helical coil section **110** and the shapeable distal end section **108**. As illustrated, a portion **110***a* of the helical coil section **110** is embedded in the atraumatic cap **120**, thus attaching the atraumatic cap **120** to the helical coil **120**. The atraumatic cap **120** forms a soldered joint **122** with the shapeable distal end section **108** by forming a solder bond with the layer of solder material **126** that is in turn bonded to the distal wire portion **124**. Because Ni—Ti alloy forms a persistent oxide layer, it can be difficult to solder Ni—Ti. Methods of manufacture will be discussed in detail below. However, because the distal wire portion **124** has a layer of solder material **126** bonded thereto, the atraumatic cap **120** can readily form a joint **122** with the shapeable distal end section **108**. By using the methods and procedures described herein, the atraumatic cap **120** can be soldered to or formed on the shapeable distal end section **108** without significant loss of the linear pseudoelastic nickel-titanium deformation behavior.

In one embodiment, portions of the guide wire device **100** are coated with a coating **118** of lubricous material such as polytetrafluoroethylene (PTFE) (sold under the trademark Teflon by du Pont, de Nemours & Co.) or other suitable lubricous coatings such as the polysiloxane coatings, polyvinylpyrrolidone (PVP), and the like.

The guide wire device **100** that includes a Ni—Ti alloy portion **104** with a shapeable distal end section **108** having linear pseudoelastic characteristics, which facilitates shaping of the distal tip section **108** of the guide wire **100**. The Ni—Ti alloy portion **104** may also include a superelastic portion proximal to the shapeable distal end section **108** to facilitate the advancing of the guide wire in a body lumen. The linear pseudoelastic and superelastic portions exhibit extensive, recoverable strain, which greatly minimizes the risk of damage to arteries during the advancement therein.

The proximal portion **102** of the guide wire device **100** is typically made from stainless steel. Stainless steel is generally significantly stronger, i.e., higher yield strength and ultimate tensile strength, than superelastic or linear pseudo elastic Ni—Ti. Suitable high strength materials include 304 or 316L stainless steel, which is a conventional material in guide wire construction.

To illustrate the foregoing points, FIG. **2** contains the elastic component of three idealized stress-strain curves for 316L stainless steel **222**, linear pseudoelastic Ni—Ti **218/220**, and non-linear pseudoelastic Ni—Ti alloy **200**. The stress/strain relationship is plotted on x-y axes, with the x axis representing strain and the y axis representing stress.

In curve **200**, when stress is applied to a specimen of a Ni—Ti alloy exhibiting non-linear pseudoelastic characteristics at a temperature at or above where the materials is in the austenitic phase, the specimen deforms elastically in region **202** until it reaches a particular stress level where the alloy then undergoes a stress-induced phase transformation from the austenitic phase to the martensitic phase (i.e., the stress-induced martensite phase). As the phase transformation progresses, the alloy undergoes significant increases in strain with little or no corresponding increases in stress. On curve **200**, this is represented by the upper, nearly flat stress plateau **204**. The strain increases while the stress from continued deformation remains essentially constant until the transformation of the austenitic phase to the martensitic phase is complete at approximately region **206**. Thereafter, further increase in stress is necessary to cause further deformation to point **208**. The martensitic metal first yields elastically upon the application of additional stress and then plastically with permanent deformation (not shown).

If the load on the specimen is removed before any permanent deformation has occurred, the martensitic Ni—Ti alloy elastically recovers and transforms back to the austenitic phase. The reduction in stress first causes a decrease in strain along region **210**. As stress reduction reaches the level at which the martensitic phase transforms essentially completely back into the austenitic phase at region **212**, the stress level in the specimen remains essentially constant to continue relieving strain along lower plateau **214** (but less than the constant stress level at which the austenitic crystalline structure transforms to the martensitic crystalline structure until the transformation back to the austenitic phase is complete); i.e., there is significant recovery in strain with only negligible corresponding stress reduction.

After the transformation back to austenite is complete, further stress reduction results in elastic strain reduction along region **216**. This ability to incur significant strain at relatively constant stress upon the application of a load and to recover from the deformation upon the removal of the load is commonly referred to as non-linear pseudoelasticity (or superelasticity).

FIG. **2** also includes a curve **218/220** representing the idealized behavior of linear pseudoelastic Ni—Ti alloy as utilized in the shapeable distal end section **108** in the present invention. The slope of curve **218/220** generally represents the Young's modulus of the linear pseudoelastic Ni—Ti alloy. Also, curve **218/220** does not contain any flat plateau stresses found in curve **200**. This stands to reason since the Ni—Ti alloy of curve **218-220** remains in the martensitic phase throughout and does not undergo any phase change. To that end, curve **218/220** shows that increasing stress begets a proportional increase in reversible strain, and a release of stress begets a proportional decrease in strain. The areas bounded by curves **200** and **218-220** represent the hysteresis in the Ni—Ti alloy.

As is apparent from comparing curve **218/220** to curve **200** in FIG. **2**, with the use of linear pseudoelastic Ni—Ti alloy, the mechanical strength of linear pseudoelastic Ni—Ti alloy and non-linear pseudoelastic Ni—Ti alloy is similar. Consequently, a major benefit of the distal end section **108** made from linear pseudoelastic Ni—Ti alloy is that it is shapeable, whereas a distal end section made from non-linear pseudoelastic Ni—Ti alloy is practically un-shapeable because it is very difficult to overstrain non-linear pseudoelastic Ni—Ti alloy.

FIG. **2** also includes curve **220** which is the elastic behavior of a standard 316L stainless steel. Stress is incrementally applied to the steel and, just prior to the metal deforming plastically, decrementally released.

III. Methods for Fabricating a Guide Wire Device

In one embodiment, a method for fabricating a guide wire device is disclosed. The method includes (1) fabricating an elongate shaft member that includes a proximal end section and a distal end section. In one embodiment, the distal end section includes a nickel-titanium alloy member that has a first cross-sectional dimension (e.g., a thickness). The method further includes (2) dipping at least a portion of the distal end section in a molten solder material to apply (e.g., coat) the molten solder material thereon, (3) cold working at least a portion of the distal end section having the solder material coated thereon, wherein the cold working yields a distal shapeable section having a linear pseudoelastic nickel-titanium microstructure, and (4) soldering the distal shapeable section and a helical coil section disposed about the distal shapeable section to an atraumatic cap without substantial loss of the linear pseudoelasticity of the distal shapeable section.

In one embodiment, fabricating an elongate shaft member that includes a proximal end section and a distal end section may include may include attaching (e.g., by welding) a proximal end section fabricated from a first material such as stainless steel to a distal end section fabricated from a second material such as nickel-titanium alloy. Alternatively, the elongate shaft member can be fabricated from a single material such as, but not limited to, a nickel-titanium alloy.

In one embodiment, fabricating an elongate shaft member may further include drawing at least a portion of the elongate shaft member through a drawing die, rolling, calendaring, grinding, or combinations thereof to form or reshape the at least a portion of the elongate shaft member and cleaning the elongate shaft member such as by ultrasonically cleaning.

Ni—Ti alloys, such as those described herein, are very difficult to solder due to the formation of a tenacious, naturally occurring oxide coating which prevents the molten solder from wetting the surface of the alloy. It has been found that by first treating the surface of the Ni—Ti alloy with molten alkali metal hydroxide, e.g., sodium, potassium, lithium or mixtures thereof to form a substantially oxide-free alloy surface and then pretinning (i.e., applying a suitable solder material, such as, a gold-tin solder, a gold-indium solder, a gold-germanium solder, a silver-tin solder, a silver-gold-tin solder, or another suitable solder) without contacting air, that Ni—Ti alloys can be readily soldered in a conventional manner. In one embodiment, solder can be applied to at least a portion of the distal end section by dipping the at least the distal end section into a bath, wherein the bath includes an upper layer of a molten metal hydroxide and a lower layer of the molten solder material. Alternatively, a layer of solder material can be applied to at least a portion of the distal end section by chemical vapor deposition (CVD), physical vapor deposition (PVD), sputter coating, and the like, and combinations thereof.

Subsequently, at least a portion of the distal end section, with the solder material applied thereto, can be cold-worked to yield a distal shapeable end section having a second cross-sectional dimension. After applying the solder material and cold working, a helical coil section can be assembled around the a distal portion of the elongate shaft member, including the distal shapeable section, and a rounded plug (i.e., an aturaumatic cap section) can be formed at the distal end of the assembly by soldering the distal shapeable section and a helical coil section disposed about the distal shapeable section to the rounded plug without substantial loss of the linear pseudoelasticity of the distal shapeable section. The pretinning followed by cold working and forming the atraumatic cap at the distal end of the elongate shaft member yields a user-shapeable distal end section that exhibits linear pseudoelastic deformation behavior without a phase transformation or onset of stress-induced martensite.

In a more specific embodiment, a method for fabricating a guide wire device that has a shapeable distal end section includes (1) providing an elongate shaft member that includes a proximal end section and a distal end section, wherein the distal end section includes a nickel-titanium alloy member, (2) grinding at least a portion of the distal end section to a first cross-sectional dimension, and (3) ultrasonically cleaning at least the distal end section. After grinding and cleaning, the method further includes (4) dipping at least a portion of the distal end section into a bath of a molten solder material, wherein the bath of molten solder material includes an upper layer of a molten metal hydroxide and a lower layer of the molten solder material, and (5) cold working at least a portion of the distal end section, wherein the cold working yields a distal shapeable section having a linear pseudoelastic nickel-titanium microstructure. After cold working at least a portion of the distal end section, the method continues with (6) ultrasonically cleaning at least the distal end section, (7) disposing a helical coil section about the distal shapeable section, and (8) forming an atraumatic cap section coupling the helical coil section and the distal shapeable section via a soldered joint, wherein the soldered joint is formed without loss of the linear elastic nickel-titanium microstructure.

Ni—Ti alloys, such as those described herein, are very difficult to solder due to the formation of a tenacious, naturally occurring oxide coating which prevents the molten solder from wetting the surface of the alloy in a manner necessary to develop a sound, essentially oxide free, soldered joint. It has been found that by first treating the surface of the Ni—Ti alloy with molten alkali metal hydroxide, e.g., a hydroxide of sodium, potassium, lithium, or mixtures thereof to form a sufficiently oxide free alloy surface and then pretinning with a suitable solder such as a gold-tin solder or the like without contacting air, that the Ni—Ti piece can be readily soldered in a conventional manner.

A presently preferred alkali metal hydroxide is a mixture of about 59% KOH and about 41% NaOH. The solder may have a melting point temperature in a range of about 150° C. to about 350° C. or about 280° C. to about 300° C. The solder may contain from about 60 to about 85% gold and the balance tin, with the presently preferred solder containing about 80% gold and about 20% tin. Other suitable solders may include gold-indium, gold-germanium, silver-tin, and silver-gold-tin.

In a presently preferred procedure, a multilayered bath is provided with an upper layer of molten alkali metal hydroxide and a lower layer of molten gold-tin solder. The part of the superelastic distal portion, which is to be soldered, is thrust into the multilayered bath through the upper surface of the molten alkali metal hydroxide which removes the oxide coating, leaving a sufficiently oxide free alloy surface, and then into the molten solder which wets the cleaned surface. When the solder solidifies upon removal from the molten solder into a thin coating on the metal alloy surface, the underlying alloy surface is protected from the oxygen-containing atmosphere. Any of the alkali metal hydroxide on the surface of the solder can be easily removed with water without detrimentally affecting either the pretinned layer or the underlying alloy surface. The pretinned Ni—Ti member is then ready for further processing and/or soldering. The pretinning procedure may be employed for soldering other metal alloys having significant titanium levels.

In one embodiment, the distal end section may be drawn and ground to a first dimension (e.g., about 0.08 mm), ultrasonically cleaned, and pretinned according to the method described above. In one embodiment, the distal end section can be dipped in the molten solder material at least a second time if a thicker coating of solder is desired or if the distal end section was not completely coated in the first dip. After pretinning, the distal end section is cold-worked, ultrasonically cleaned, and soldered using conventional soldering procedures.

Suitable examples of cold working procedures that can be used to cold work the distal end section include, but are not limited to, high force flattening, stamping, rolling, calendaring, and combinations thereof. High force flattening is the currently preferred cold-working procedure.

The cold working procedure and the degree of cold working is important for obtaining a distal end section that is shapeable by a user. This is graphically illustrated in FIG. **3**. FIG. **3** is a diagram schematically illustrating the relationship between degree of cold work and shapeability of a Ni—Ti alloy. As can be seen in FIG. **3**, when superelastic Ni—Ti has little or no cold work, the material has too much superelastic character to be shaped. At the other end of the spectrum, Ni—Ti alloy material that has too much cold work becomes essentially unshapeable by manual means because its yield stress is too high. That is, highly cold-worked Ni—Ti alloy may be shapeable, but the stress that must be exceeded to exceed the elastic limit of the material (i.e., the yield stress) is too high to be conveniently shaped by hand. In the middle of the spectrum, there is shown a region where the degree of cold work is such that the Ni—Ti material is highly shapeable.

Specific examples of this phenomenon are illustrated in FIG. **4**, which illustrates the yield stress of samples of Ni—Ti alloy having various degrees of cold work. The as-ground (0.08 mm) sample is illustrated at curve **402**. The superelastic, as-ground material cannot be permanently deformed with any degree of reliability. Curves **404-410** illustrate the effect associated with increasing amounts of cold work. The sample illustrated in curve **404** was flattened from the as-ground diameter of about 0.08 mm to about 0.045 mm, which corresponds to about 45% cold work. The sample illustrated in curve **404** has a yield stress of about 1200 MPa (~175 ksi). The samples illustrated in curves **406** and **408** were flattened from the as-ground diameter of about 0.08 mm to about 0.041 mm and 0.036 mm (respectively), which corresponds to about 49-55% cold work. The samples illustrated in curves **406** and **408** have yield stresses of about 1900 MPa (~275 ksi). The sample illustrated in curve **410** was flattened from the as-ground diameter of about 0.08 mm to about 0.028 mm, which corresponds to about 65% cold work. The sample illustrated in curve **410** has a yield stress of about 2070 MPa (~300 ksi).

Based on the results illustrated in FIG. **4**, the distal shapeable section can be cold-worked to have a yield stress in a range of about 690 MPa (~100 ksi) to about 2070 MPa (~300 ksi) or about 1034 MPa (~150 ksi) to about 1380 MPa (~200 ksi). Yield stresses in these ranges are obtained when the distal shapeable section that has a cold-worked microstructure that includes about 25% to about 65% cold work, about 40% to about 50% cold work, or about 45% cold work.

The linear pseudoelastic microstructure can be lost if the Ni—Ti material is heated after cold working. This is illustrated in FIG. **5**, which shows the progressive loss of linear pseudoelastic character of Ni—Ti alloy as a result of moderate heat exposure for varying amounts of time. FIG. **5** illustrates the loss of cold work in three samples of cold-worked Ni—Ti alloy having been exposed to 300° C. heat treatment for 2 minutes, 20 minutes, and 180 minutes. Curves in region **500** show more linear pseudoelastic behavior, while curves in region **510** show more superelastic behavior. All curves show potentially significant loss of cold work induced linear pseudoelastic behavior.

Comparing the results of FIGS. **4** and **5**, it is apparent why it is important to pretin and then cold work as opposed to cold working followed by pretinning. That is, it can be seen that the yield stress is relatively sensitive to the amount of cold work. For example, samples **406** and **408** have relatively similar amount of cold work, yet their yield stresses are considerably different. In order to obtain a distal shapeable section that can be reliable shaped, it is important to carefully select the amount of cold work. On the flip side, it is important to not lose that cold work by pretinning after cold working.

While it is believed that pretinning after cold working may lead to loss of cold work, it is not believed that soldering leads to significant loss of cold work in the distal shapeable section. This is believed to be due to the fact that soldering involves only localized application heat as opposed to solder dipping, which involves general application of heat that could lead to potentially significant loss of cold work induced linear pseudoelastic behavior.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A shapeable medical device configured to allow a practitioner to shape a distal end to a desired shape for tracking through a patient's vasculature, the shapeable medical device comprising:

an elongate shaft member comprising:

an elongate proximal portion;

a distal portion extending distally from the elongate proximal portion, the distal portion comprising a distal end portion comprising a proximal end section and a practitioner-shapeable distal end section, wherein the proximal end section is formed of a material that does not exhibit superelasticity and the practitioner-shapeable distal end section (i) being formed of a nickel titanium alloy, (ii) in a martensite phase at body temperature and having a stress-strain curve without any flat plateau stresses, (iii) with a metallic material applied over and coating an entirety of the nickel titanium alloy and a portion of the proximal end section of the distal end portion, a proximal terminal end of the metallic material being distal a proximal terminal end of the proximal end section, (iv) such that the practitioner-shapeable distal end section does not exhibit a phase transformation or onset of stress-induced martensite as the practitioner-shapeable distal end section is stressed and is linear pseudoelastic;

a second distal portion between the proximal end section and the practitioner-shapeable distal end section, wherein the second distal portion between the proximal end section and the distal end section comprises a superelastic nickel-titanium alloy, and wherein (i) the proximal end section comprises a material that does not exhibit superelasticity and (ii) the distal end section is linear pseudoelastic;

a helical coil section disposed around at least the practitioner-shapeable distal end section; and

an atraumatic cap section attached to the helical coil section and the metallic material of the practitioner-shapeable distal end section,

wherein a portion of the helical coil is embedded in the atraumatic cap section and the practitioner-shapeable distal end section has a yield stress from 100 ksi to 300 ksi and exhibits 20% to 90% cold work.

2. The shapeable medical device of claim **1**, wherein the elongate shaft member comprises stainless steel, a superelastic nickel-titanium alloy, or a combination thereof.

3. The shapeable medical device of claim **1**, wherein the practitioner-shapeable distal end section has a yield stress in a range of 150 ksi to 225 ksi.

4. The shapeable medical device of claim **1**, wherein the practitioner-shapeable distal end section has a yield stress in a range of 150 ksi to 200 ksi.

5. The shapeable guide wire device of claim **1**, wherein a core of the distal end section surrounded by the metallic material consists of the nickel titanium alloy.

6. The shapeable medical device of claim **1**, wherein the practitioner-shapeable distal end section has a yield stress in a range of 150 ksi to 200 ksi and the nickel-titanium alloy exhibits 40% to 50% cold work.

7. The shapeable medical device of claim **1**, wherein the atraumatic cap section comprises a cap of solder and wherein the solder material includes a eutectic alloy.

8. The shapeable medical device of claim **7**, wherein the eutectic alloy comprises a gold-tin solder, a gold-indium solder, a gold-germanium solder, a silver-tin solder, or a silver-gold-tin solder.

9. The shapeable medical device of claim **7**, wherein the gold-tin solder includes 80 weight % (wt %) gold and 20 wt % tin.

10. The shapeable medical device of claim **1**, wherein the atraumatic cap section comprises a cap of solder soldered to the helical coil section and the practitioner-shapeable distal end section.

11. The shapeable medical device of claim **1**, wherein the metallic material has a melting temperature of about 150° C.

12. The shapeable medical device of claim **1**, wherein a distal section of the helical coil section is made of radiopaque material.

13. The shapeable medical device of claim **1**, wherein the helical coil section is secured to the distal portion at a proximal location and at an intermediate location.

14. The shapeable medical device of claim **1**, wherein one or more portions of the shapeable medical device are coated with a lubricous material.

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